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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA LTD., AUROBINDO PHARMA LLC, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, Defendants.	Consolidated Civil Action No. 20-10172 (JXN)(MAH) CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

[PROPOSED] JOINT PRETRIAL ORDER

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A final pretrial conference having been held before the Honorable Michael A. Hammer, U.S.M.J., and Walsh Pizzi O'Reilly Falanga LLP and Williams & Connolly LLP having appeared for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, "Plaintiffs" or "Teva"); Rivkin Radler LLP and Knobbe, Martens, Olson & Bear, LLP having appeared for Defendant Cipla Ltd. ("Cipla"); and McNeely Hare & War LLP having appeared for Defendants Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo")[1], the following Final Pretrial Order is hereby entered:

1. JURISDICTION

This is an action for patent infringement under 35 U.S.C. § 271 and for declaratory and injunctive relief. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). This Court has authority to grant declaratory relief under 28 U.S.C. §§ 2201 and 2202.

The parties do not dispute personal jurisdiction or venue for the purposes of this action only.

2. PENDING/CONTEMPLATED MOTIONS

The parties' disputes regarding claim construction remain pending; briefing is complete, the Court held a claim construction hearing on November 30, 2021, and the parties are awaiting the Court's ruling.

The parties do not anticipate filing Daubert motions at this time.

Motions in limine and responses will be served on agreed upon dates, and those motions that cannot be resolved after conferral will be filed at an agreed upon time in advance of the trial date.

[1] Cipla and Aurobindo are herein collectively referred to as "Defendants."

Teva's Contemplated Motions in Limine:

- Motion in Limine to Exclude Evidence and Testimony that the '406 Publication Discloses the Inhaler Used in Defendants' ANDA Products.

    - **Teva's Position:** Defendants assert, as the basis for their ensnarement defense and certain invalidity defenses, that they "practice" the '406 Publication. However, there is no record evidence (adduced by Defendants or otherwise) that the inhaler bodies used in their ANDA Products—which contain critical features of the Asserted Claims of the '289 and '587 Patents—are described in the '406 Publication. To the contrary, Defendants' only expert confirmed at his deposition that the '406 Publication is a dose "counter patent" and does ***not*** disclose the inhaler bodies used in Defendants' ANDA Products. Defendants' response—that the '406 Publication need not disclose the *exact* inhaler body used in Defendants' ANDA Products in order for Defendants to "practice" the '406 Publication—misses the point. Defendants' expert's admissions leave him without any basis to opine that the inhaler bodies disclosed in the '406 Publication are the same as, consistent with, or otherwise "encompass" those used by Defendants' ANDA Products and those required by many of the Asserted claims. Accordingly, Defendants should be barred from presenting argument or evidence that every claimed feature of their ANDA Product is taught by the '406 Publication.

    - **Defendants' Position:**[2] The '406 Publication plainly discloses use of the dose counter with an inhaler body, an element that Defendants' expert addressed at length in his expert report with respect to at least the claims of the '289, '587, and the '156 Patents. In addition, numerous claims, including most asserted claims of the '156 Patent and all asserted claims of the '808 Patent are directed to dose counters and do not include a requirement for an inhaler body, or at most, require a generic inhaler body – which the '406 Publication discloses and which Defendants' expert addressed as being the dose counter practiced by Defendants ANDA Product in extensive detail. The '406 Publication need not disclose the exact inhaler body that Defendants use, it need only disclose an inhaler body that encompasses Defendants' inhaler for Defendants to be practicing the disclosure of the '406 Publication. Defendants' expert reports include extensive testimony regarding the disclosure of an inhaler body in the '406 Publication, and Plaintiffs' attempt to rely on a single out of context

[2] Despite the parties' agreement that Plaintiffs would provide their portion of the Pretrial Order, including proposed motions in limine on August 12, Plaintiffs initially stated that they had no such motions to file, then reviewed Defendants' timely proposed motions and then waited until the August 26 exchange to first identify this meritless motion in limine. Plaintiffs should not be allowed to present their belated and meritless proposed motion in limine due to their failure to comply with the parties agreed upon exchange schedule.

sentence regarding a narrow issue (particular disclosure of an inhaler body) from the deposition to prevent testimony regarding a broad topic (including the disclose of the dose counter) is improper. Accordingly, Plaintiffs motion in limine should be denied.

- Motion in Limine to Exclude Evidence and Testimony Regarding Undisclosed Obviousness Theories.

  - **Teva's Position:**[3] Defendants' expert opined that the Asserted Claims would have been obvious based on the nine specific reference combinations, listed below. Despite this, Defendants now style their obviousness theories as relying on the references disclosed in their expert reports in combination with the "knowledge of the POSA." Defendants should not be permitted to use such "background knowledge" to expand their obviousness theories beyond the specific references and rationales identified in their expert disclosures. Defendants' cited cases do not support their attempts to circumvent these disclosure obligations. Whether and to what extent a POSA's knowledge may bear on an obviousness analysis is beside the point. Where a party seeks to rely on a specific combination of references—as in this case—it cannot later supplement and expand those combinations with vague reference to the POSA's "knowledge" absent timely disclosure (i.e., during discovery) of how and why the POSA would combine such knowledge with the prior art. *See, e.g., ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327-28 (Fed. Cir. 2012) (opinion insufficient where expert "failed to explain how specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, or how any specific combination would operate or read on the asserted claims"); *Avnet, Inc. v. Motio, Inc.*, C.A. No. 12-2100-SIS, 2016 WL 3365430, at *6 (N.D. Ill. June 15, 2016) (reference not "background" when used to disclose a claim limitation). Defendants' response suggests that is precisely what they seek to do here. Thus, Teva will move to preclude Defendants from asserting at trial any obviousness theories other than those that they timely disclosed:
    - '289 and '587 Patents:
      - Obviousness over the '406 Publication
      - Obviousness over the '021 Publication

[3] Defendants complain that Teva did not propose its motions in limine on August 12, 2022, during the first round of pretrial disclosures, but instead proposed them on August 26, after Teva received Defendants' pretrial disclosures. That is precisely the point. Teva's motions are predicated on the positions that Defendants have taken in the parties' pretrial exchanges; thus, Teva proposed them after receiving and evaluating Defendants' positions. Indeed, both Teva and Defendants have continually updated their pretrial documents throughout the exchange process without objection. Furthermore, Defendants have suffered no prejudice—these motions will be briefed at a later date in the event they cannot be resolved, and Defendants will have as much notice and opportunity to respond as Teva does throughout that process.

- Obviousness over the '406 Publication in combination with the '514 Publication
- Obviousness over the '021 Publication in combination with the '514 Publication

▪ '156 Patent:
- Obviousness over the '552 Publication
- Obviousness over the '406 Publication

▪ '808 Patent:
- Obviousness over the '552 Publication
- Obviousness over the '950 Publication
- Obviousness over the '406 Publication

o **Defendants' Position:**[4] Teva's proposed motion in limine is based on a fundamental lack of understanding of black letter patent law regarding obviousness, the obviousness analysis and a plain misrepresentation of Defendants' expert reports. First, Plaintiffs' position is unreasonable and inconsistent with Supreme Court precedent. The Supreme Court, in 2007, emphasized the relevance of "the background knowledge posted by a person having skill in the art" in an obviousness analysis. *KSR International co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007). The Federal Circuit has also confirmed that the general knowledge of a POSA is relied upon to render a claimed invention obvious and can be used to supply missing claim limitations. *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330 1337 (Fed. Cir. 2020) ("the inquiry into whether any 'differences' between the invention and the prior art would have rendered the invention obvious to a skilled artisan necessarily depends on such artisan's knowledge."); *see also Dow Jones & Co. v. Ablaise, Ltd*, 606 F.3d 1338, 1349 (Fed. Cir. 2010) (the obviousness "analysis requires an assessment of the background knowledge possessed by a person having ordinary skill in the art"). Defendants' expert provided extensive background knowledge in his reports showing the knowledge of the POSA and it would be improper and inconsistent with controlling precedent to exclude the extensive evidence of the knowledge of the POSA. Second, Plaintiffs' motion appears to be improperly based on the table of contents of Defendants' expert reports, rather than the content of the reports. For example, the actual discussions in the expert reports extensively detail the knowledge of the POSA and how that knowledge in in combination with the listed reference renders a limitation obvious. The conclusion of the single-reference obviousness sections, for example

[4] Despite the parties' agreement that Plaintiffs would provide their portion of the Pretrial Order, including proposed motions in limine on August 12, Plaintiffs initially stated that they had no such motions to file, then reviewed Defendants' timely proposed motions and then waited until the August 26 exchange to first identify this meritless motion in limine. Plaintiffs should not be allowed to present their belated and meritless proposed motion in limine due to their failure to comply with the parties agreed upon exchange schedule.

repeatedly state: "Therefore this limitation would have been obvious over [prior art reference] ***and the knowledge of the POSA***." For at least these reasons, Plaintiffs' baseless motion in limine should be denied.

Defendants' Contemplated Motions in Limine:

- Motion in Limine to Exclude Evidence and Testimony that Claim 13 of the '587 Patent, and Claims 14-22 which depend therefrom are Infringed Literally or Under the Doctrine of Equivalents.

    - **Defendants' Position:** Defendants intend to move to preclude Plaintiffs from arguing infringement of Claim 13, and all claims which depend therefrom. Plaintiffs failed to provide any evidence or expert testimony through its reports or deposition that the Claim 13 limitation "first inner wall support formation extends from the main surface of the inner wall to the aperture" is present literally or under the doctrine of equivalents. Plaintiffs' attempt to cite the Lewis Opening Report in response to Defendants' proposed motion only confirms their failure to address a key limitation. For example, Lewis Opening Report, ¶¶ 54-118 address claim 1 of the '289 patent, which does not include the disputed limitation. Similarly, their reliance on ¶¶ 123-39 is misplaced. Paragraphs 123-39 address the '289 patent, claim 3, which also does not include the disputed limitation. These paragraphs include no testimony that Defendants' ANDA Product includes a "first inner wall support formation [that] ***extends from the main surface of the inner wall to the aperture***." The sole analysis of claim 13 of the '589 patent recites: "Claims 1 and 3 of the recite every limitation of claim 13 of the '587 Patent. . . . Thus in my opinion, [Defendants'] ANDA Product satisfies every limitation of claim 13 of the '587 Patent." *See* Lewis Opening Report at ¶ 196. If Dr. Lewis presents this testimony at trial, as Plaintiffs contend, Plaintiffs cannot meet their burden of proving infringement of every limitation of claim 13 of the '587 Patent. Moreover, Plaintiffs may not introduce evidence or testimony on this limitation for the first time at trial. Plaintiffs' argument that "Defendants will have an opportunity to challenge the basis for his opinions on cross-examination," is incorrect and misses the point. Dr. Lewis never presented evidence or testimony on this limitation, and Plaintiffs are now attempting to ambush Defendants, at trial, with a new basis for infringement that was never articulated by their expert. Such tactics are improper, and avoiding such surprise evidence is precisely the reason for expert reports and discovery. As such, Plaintiffs should be barred from arguing or introducing evidence that Defendants infringe, literally or under the doctrine of equivalents, Claim 13 of the '587 patent, or claims 14-22 which depend therefrom.

    - **Teva's Position:** Defendants' argument is a motion for summary judgment styled as a motion in limine. There is no disagreement about the way Defendants' device operates, and Teva has adduced sufficient evidence that

Defendants' device operates in such a way to infringe Claims 13 of the '587 patent (and Claims 14-22 which depend therefrom). Relying on Defendants' production and samples, Teva's expert, Dr. David Lewis, explained at length why Defendants' ANDA Products satisfied the requirements of the claim, *see, e.g.*, Lewis Opening Rep. (Cipla) ¶¶ 54-118 ('289 Patent, Claim 1), ¶¶ 123-39 ('587 Patent, Claim 13), including under both Teva's and Defendants' proposed constructions of relevant claim terms, *see, e.g.*, Lewis Opening Rep. (Cipla) ¶¶ 112-18. He therefore concluded that Defendants infringed Claim 13 of the '587 Patent. *See, e.g.*, Lewis Opening Rep. (Cipla) ¶¶ 195-98. Defendants' assertion that the cited paragraphs do not address the relevant issue begs the question of their own construction and application of the claim language in question, not to mention Court's assessment of the evidence at trial. Dr. Lewis will present similar testimony at trial in a manner well supported by his report and far from the purported "ambush" of which Defendants complain. There is no valid legal basis to prevent such testimony, and Defendants will have an opportunity to challenge the basis for his opinions on cross-examination.

- Motion in Limine to Exclude Evidence and Argument Contrary to the Prosecution History.

    - **Defendants' Position:** Defendants intend to move to preclude Plaintiffs from arguing or introducing into evidence that the datum plane can be drawn at the top of the valve stem block, as required by Asserted Claims 1, 9 and 11-13 of the U.S. Patent No. 10,086,156. During prosecution of the application leading to the '156 patent, the applicants surrendered patent coverage for devices in which the actuator pawl is above the datum plane in the canister fire configuration. They obtained allowance by arguing to the examiner that the prior art did not disclose an actuator pawl that passed below the datum plane in the fire configuration, when the datum plane was placed in a particular location shown by Figure 9 of the '156 Patent. Allowing Plaintiffs to place the datum plane at the top of the valve stem block (higher than argued to the examiner) as they now propose, would improperly expand the scope of the patent beyond what was allowed by the examiner. As such, Plaintiffs should be barred from arguing or introducing into evidence that the datum plane can be drawn at the top of the valve stem block. Plaintiffs also failed to disclose the location of the datum plane in Plaintiffs' infringement contentions, and for this additional reason, should be precluded from arguing its location now. Plaintiffs attempt to characterize Defendants' motion as a "do-over" of claim construction, merely highlights Plaintiffs' own gamesmanship in waiting until after claim construction (and well after exchange of infringement and invalidity contentions) to first argue that the datum plane could be drawn at the top of the valve stem block.

    - **Teva's Position:** Defendants' motion improperly seeks a "do-over" of their claim construction submissions regarding the "datum plane" limitation.

During claim construction proceedings, Defendants argued that the '156 Patent's prosecution history supported a narrow construction of that limitation. Teva offered a contrary construction. The parties completed briefing on that issue in September 2021, and the Court held a hearing in November 2021. Defendants should not be permitted to burden the Court with additional claim construction briefing in the guise of a motion in limine. Defendants' motion is also meritless. In his reports, Dr. Lewis explained why Defendants' ANDA Products infringed the "datum plane" limitation under ***either*** of Teva or Defendants proposed constructions. Thus, even if Defendants were correct about the meaning of the prosecution history (and they are not), Teva's expert's opinion still stands. Contrary to Defendants' contention, there was nothing improper about the timing of that disclosure. Teva's expert provided his opinions (which were predicated on additional testing, and fully consistent with the claim construction positions Teva had long been advancing) at the time specified in the Court's Scheduling Order for expert disclosures. Notwithstanding Teva's timely disclosure, Defendants served a belated, supplemental report directed to this limitation in particular, obviating any possible prejudice. That Defendants' expert disagrees with Teva's expert simply reflects that the issue remains for trial. Rather than deciding the issue on an incomplete record, the Court should permit the parties and their experts to address the issue at trial, during which the Court will have the opportunity to weigh competing evidence and expert testimony.

- Motion in Limine to Exclude Evidence and Argument of a Hypothetical Claim that Allegedly Encompasses the Accused Products without Ensnaring Prior Art.

    - **Defendants' Position:** Defendants intend to move to preclude Plaintiffs from arguing a hypothetical claim theory in response to Defendants' ensnarement arguments. Plaintiffs have been on notice of Defendants' ensnarement claims since December 2020. Plaintiffs even noted the need for a Person of Skill in the Art ("POSA") to testify whether a hypothetical claim that would read on the accused product would have been obvious or anticipated by the prior art, in their January 2021 reply to Cipla's Rule 12(c) motion. However, despite having the opportunity to present the required hypothetical claim in their contentions and through their expert during expert discovery, Plaintiffs failed to do so. As such, Plaintiffs should be barred from arguing or introducing into evidence a hypothetical claim in rebuttal to Defendants' ensnarement allegations for the first time at trial.

    - **Teva's Position:** Defendants have put forward an "ensnarement" defense to infringement under the doctrine of equivalents ("DOE"), arguing that expanding the scope of the claims to encompass their products would improperly encompass or "ensnare" the prior art. Defendants' proposed motion seeks to preclude Teva from analyzing that defense using a "hypothetical claim" analysis—an optional framework that, as its name suggests, compares a "hypothetical claim" encompassing the accused

product to the prior art. Defendants' motion mischaracterizes both the proper application of that framework and Teva's disclosures regarding the scope of its theories of infringement under DOE. ***First***, Defendants' position, that Teva need have formally announced a hypothetical claim at this juncture, puts the cart before the horse—Teva cannot reasonably be expected to articulate a hypothetical claim that appropriately expands the claim scope before the Court has determined what that literal scope is in its claim construction ruling. Indeed, if the Court adopts Teva's constructions, Defendants' ANDA Products will literally infringe many of the Asserted Claims, obviating the need for a DOE and ensnarement analysis for those claims. ***Second***, Teva's disclosures are sufficient. Teva has placed Defendants on notice of the subject matter Teva asserts would be covered by its DOE theories, including by advancing constructions that literally encompass Defendants' ANDA Products and/or by explaining, via its expert, Dr. Lewis, the basis for equivalence between Defendants' ANDA Products and the claims even as Defendants would construe them. Dr. Lewis further addressed Defendants' sole basis for asserting ensnarement—i.e., that the '406 Publication would render obvious the Asserted Claims, when construed to encompass Defendants' ANDA Products. Should Teva present a DOE case, and should the Court would find it helpful to apply that optional approach, Teva is prepared to present such an analysis in its pre- or post-trial briefing.

3. THE PARTIES' CONTENTIONS

Asserted Claims.

Teva asserts that Defendants infringe the following Asserted Claims:

- Claims 1-8 of U.S. Patent No. 9,463,289;
- Claims 1-8 and 11-22 of U.S. Patent No. 9,808,587;
- Claims 1, 9, and 11-13 of U.S. Patent No. 10,086,156; and
- Claims 1, 27, and 28 of U.S. Patent No. 10,561,808.

Accused Products.

Teva accuses the products described in Cipla's ANDA No. 211434 and Aurobindo's ANDA No. 214418 of infringing the Asserted Claims.

Doctrine of Equivalents.

Teva's Position:

Teva may rely on the doctrine of equivalents to establish infringement of certain claims. The identity of those claims depends upon the Court's claim construction decision. In the absence of a claim construction order, Teva's expert opined that Defendants' ANDA Products infringed each of the Asserted Claims under the doctrine of equivalents. Teva's expert will be prepared to present testimony consistent with those opinions at trial. Should the Court's claim construction decision obviate or otherwise alter Teva's need to assert infringement under the doctrine of equivalents, Teva will promptly identify within 10 days the claims for which its infringement theory depends on the doctrine of equivalents upon receipt of that order.

Defendants' Position:

The Parties agreed upon a procedure for exchanging pre-trial documents and positions, which did not include any agreement that Plaintiffs could delay their disclosure of claims for which they may rely on the doctrine of equivalents. Accordingly, because Plaintiffs failed to identify any allegations of infringement under the doctrine of infringement, they have waived the right to rely on any argument that Defendants infringe an Asserted Claim under the doctrine of equivalents.

However, if the Court allows Plaintiffs to belatedly identify doctrine of equivalents theories, Defendants should be provided 10 days from Plaintiffs' identification of infringement theories depending on the doctrine of equivalents to amend this Final Pretrial Order to address Plaintiffs belated identification of doctrine of equivalence theories, including to identify contested and undisputed facts relevant to prosecution history estoppel, claim vitiation, ensnarement, and Plaintiffs' function, way, result or insubstantial differences analyses.

Infringement Theory.

Teva's infringement theories are theories of direct infringement. Teva does not assert any theory of indirect infringement.

Type of Damages.

Teva seeks declaratory and injunctive relief, as well as award of attorney's fees and costs. Specifically, as to Cipla, Teva seeks:

- A declaration and judgment that Cipla infringes the Asserted Claims of the '289, '587, '156, and '808 Patents.
- A declaration and judgment that the Asserted Claims of the '289, '587, '156, and '808 Patents are not invalid.
- An order, under 35 U.S.C. § 271(e)(4)(A), that the effective date of the U.S. Food & Drug Administration's ("FDA's") approval of Cipla's ANDA shall be a date not earlier than the latest expiration date of the '289, '587, '156, and '808 Patents, including any adjustments, extensions, or exclusivities.
- An injunction, under 35 U.S.C. §§ 271(e)(4)(B) and 283, prohibiting Cipla and its officers, agents, servants, and employees from manufacturing, using, offering for sale, selling, or importing into the United States Cipla's ANDA Product prior to the latest expiration date of the '289, '587, '156, and '808 Patents, including any adjustments, extensions, or exclusivities.
- An award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.
- An award of costs under Federal Rule of Civil Procedure 54(d)(1).

Specifically, as to Aurobindo, Teva seeks:

- A declaration and judgment that Aurobindo infringes the asserted claims of the '289, '587, '156, and '808 Patents.
- A declaration and judgment that the asserted claims of the '289, '587, '156, and '808 Patents are not invalid.
- An order, under 35 U.S.C. § 271(e)(4)(A), that the effective date of Aurobindo's ANDA shall be a date that is not earlier than the latest expiration date of the '289, '587, '156, and '808 Patents, including any adjustments, extensions, or exclusivities.

- An injunction, under 35 U.S.C. §§ 271(e)(4)(B) and 283, prohibiting Aurobindo and its officers, agents, servants, and employees from manufacturing, using, offering for sale, selling, or importing into the United States Aurobindo's ANDA Product prior to the latest expiration date of the '289, '587, '156, and '808 Patents, including any adjustments, extensions, or exclusivities.

- An award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

- An award of costs under Federal Rule of Civil Procedure 54(d)(1).

Cipla seeks the following relief:

- A declaration and judgment that the manufacture, import, use, sale, and or/offer to sell Cipla's ANDA Product, has not, does not, and will not infringe (literally or under the doctrine of equivalents) any asserted claim of the '289, '587, '156, and '808 Patents.

- A declaration and judgment that each asserted claim of the '289, '587, '156, and '808 Patents is invalid.

- A declaration and judgment that Cipla has the lawful right to manufacture, import, use, sell, and/or offer to sell Cipla's ANDA Product in the United States following approval from the FDA.

- An injunction prohibiting Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them be preliminarily and permanently enjoined from threatening or initiating litigation alleging infringement of the '289, '587, '156, and '808 Patents against Cipla or any of its customers, dealers, or supplies, or any prospective or present sellers, dealers, distributors, or customers, or charging them, orally or in writing, with infringement of the '289, '587, '156, and '808 Patents.

- An award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

- An award of costs under Federal Rule of Civil Procedure 54(d)(1).

Aurobindo seeks the following relief:

- A declaration and judgment that the manufacture, import, use, sale, and or/offer to sell Aurobindo's ANDA Product, has not, does not, and will not infringe (literally or under the doctrine of equivalents) any asserted claim of the '289, '587, '156, and '808 Patents.

- A declaration and judgment that each asserted claim of the '289, '587, '156, and '808 Patents is invalid.

- A declaration and judgment that Aurobindo has the lawful right to manufacture, import, use, sell, and/or offer to sell Aurobindo's ANDA Product in the United States following approval from the FDA.

- An injunction prohibiting Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them be preliminarily and permanently enjoined from threatening or initiating litigation alleging infringement of the '289, '587, '156, and '808 Patents against Aurobindo or any of its customers, dealers, or supplies, or any prospective or present sellers, dealers, distributors, or customers, or charging them, orally or in writing, with infringement of the '289, '587, '156, and '808 Patents.

- An award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

- An award of costs under Federal Rule of Civil Procedure 54(d)(1).

"Objective Indicia."

Teva asserts that numerous objective indicia of non-obviousness support the patentability of the Asserted Claims, specifically:

- Long-felt, Unmet Need;

- Failure of Others;

- Industry Acceptance;

- Praise; and

- Copying.

Defendants dispute that any asserted objective indicia of non-obviousness support the patentability of the Asserted Claims.

4. STIPULATION OF FACTS

Definitions Applicable to Stipulation of Facts

1. As used herein, the term "Cipla" means Cipla Ltd.

2. As used herein, the term "Aurobindo" means Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC.

3. As used herein, the term "Defendants" means Cipla and Aurobindo.

4. As used herein, the terms "Teva" and "Plaintiffs" mean Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

5. As used herein, the term "Cipla's ANDA Product" means the products described in Cipla's ANDA No. 211434 and any supplements or amendments thereto.

6. As used herein, the term "Aurobindo's ANDA Product" means the products described in Aurobindo's ANDA No. 214418 and any supplements or amendments thereto.

7. As used herein, the term "Defendants' ANDA Products" means Cipla's ANDA Product and Aurobindo's ANDA Product.

8. As used herein, the term "the '289 Patent" means U.S. Patent No. 9,463,289.

9. As used herein, the term "the '587 Patent" means U.S. Patent No. 9,808,587.

10. As used herein, the term "the '156 Patent" means U.S. Patent No. 10,086,156.

11. As used herein, the term "the '808 Patent" means U.S. Patent No. 10,561,808.

12. As used herein, the term "Asserted Patents" means the '289 Patent, the '587 Patent, the '156 Patent, and the '808 Patent.

13. As used herein, the term "Asserted Claims" means the Asserted Claims set forth in Section 3.

Undisputed Facts

1. Teva holds all rights, title, and interest in each of the Asserted Patents.

2. Each of the Asserted Patents is listed in the FDA's Approved Products with Therapeutic Equivalents ("Orange Book") in connection with Teva's Qvar® HFA with Dose Counter drug product.

3. Each of Defendants' ANDA Products comprises an inhaler for metered dose inhalation.

4. The inhaler of each of Defendants' ANDA Products comprises a main body having a canister housing.

5. The inhaler of each of Defendants' ANDA Products comprises a medicament canister.

6. The medicament canister of each of Defendants' ANDA Products is moveable relative to the canister housing.

7. The medicament canister of each of Defendants' ANDA Products is retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister.

8. Each of Defendants' ANDA Products comprises a dose counter.

9. The canister housing of each of Defendants' ANDA Products has an inner wall.

10. The inner wall of the canister housing of each of Defendants' ANDA Products has a plurality of ribs.

11. The canister housing of each of Defendants' ANDA Products has a longitudinal axis X which passes through the center of the central outlet port.

12. The medicament canister of each of Defendants' ANDA Products is moveable relative to the dose counter.

13. Each of Defendants' ANDA Products comprises a dose counter for a metered dose inhaler.

14. Each of Defendants' ANDA Products comprises a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug.

15. Each of Defendants' ANDA Products comprises a dose counter for an inhaler.

16. For purposes of this action only, the parties agree that the following references qualify as prior art to the Asserted Claims:

a. PTX-097, Fink et al., *Problems with Inhaler Use: A Call for Improved Clinician and Patient Education*, Respir. Care, 50(10):1360-1375 (2005) ("Fink 2005"), a copy of which has been produced at CIPLA-BDI_0184184-95.

b. PTX-122, Ogren et al., *How Patients Determine When to Replace Their Metered Dose Inhalers*, Annals Allergy, Asthma & Immunology, 75:485-498 (Dec. 1995) ("Ogren 1995"), a copy of which has been produced at TEVADOC-00000011-15.

c. PTX-125, Sander et al., *Dose Counting and the Use of Pressurized Metered-Dose Inhalers: Running on Empty*, Annals Allergy, Asthma & Immunology, 97:34-38 (Jul. 2006) ("Sander 2006"), a copy of which has been produced at TEVADOC-00000046-50.

d. PTX-137, Hess, *Aerosol Delivery Devices in the Treatment of Asthma*, Respir. Care, 53(6):699-723 (2008) ("Hess 2008"), a copy of which has been produced at TEVADOC-00000379-405

e. PTX-138, Holt et al., *Metered Dose Inhalers: A Need for Dose Counters*, Respirology, 10:105-106 (2005) ("Holt 2005"), a copy of which has been produced at TEVADOC-00000406-07.

f. PTX-160, Williams et al., *The Doser External Counting Device*, Chest, 116(5):1499 (1999) ("Williams 1999"), a copy of which has been produced at TEVADOC-00000744.

g. PTX-402, U.S. Food & Drug Admin, Guidance for Industry, Integration of Dose-Counting Mechanisms Into MDI Drug Products (Mar. 2003) ("FDA Guidance 2003"), a copy of which has been produced at TEVAQVAR-00032573-79.

h. DX-161, International Patent Publication No. WO 2007/124406 ("the '406 Publication"), a copy of which has been produced at CIPLA-BDI_0184003-99.

i. DX-162, International Patent Publication No. WO 2008/119552 ("the '552 Publication"), a copy of which has been produced at CIPLA-BDI_0184693-720.

j. DX-165, International Patent Publication No. WO 2003/101514 ("the '514 Publication"), a copy of which has been produced at CIPLA-BDI_0184421-469.

k. DX-155, United States Patent Application Publication No. US 2002/0047021 ("the '021 Publication"), a copy of which has been produced at CIPLA-BDI_0184944-73.

l. DX-174, U.S. Design Patent No. D416,998 ("the '998 Patent"), a copy of which has been produced at CIPLA-BDI_0184391-95, issued on November 23, 1999.

m. DX-159, United States Patent Application Publication No. US 2002/0078950 ("the '950 Publication"), a copy of which has been produced at CIPLA-BDI_0184200-213.

n. DX-153, United States Patent Application Publication US 2006/0289008 ("the '008 Publication"), a copy of which has been produced at CIPLA-BDI_0184315-328.

o. DX-137, United States Patent No. 4,817,822 ("the '822 Patent"), a copy of which has been produced at CIPLA-BDI_0184347-356.

p. DX-138, United States Patent No. 7,407,066 ("the '066 Patent"), a copy of which has been produced at CIPLA-BDI_0184372-378.

q. DX-148, United States Patent No. 6,446,627 ("the '627 Patent"), a copy of which has been produced at CIPLA-BDI_0156580-594.

r. DX-139, United States Patent No. 8,584,668 ("the '668 Patent"), a copy of which has been produced at CIPLA-BDI_018379-390.

s. DX-172, International Patent Publication No. WO 2004/060260 ("the '260 Publication").

t. DX-163, United States Patent Publication No. US 2005/0087191 ("the '191 Publication").

u. DX-164, International Patent Publication No. WO 2007/103712 ("the '712 Publication").

v. DX-166, European Patent Publication No. EP 1,369,139 ("the '139 Publication"), a copy of which has been produced at CIPLA-BDI_0184888-912.

w. DX-167, United Kingdom Patent Publication No. GB 2,320,489 ("GB '489"), a copy of which has been produced at CIPLA-BDI_0184913-943.

x. DX-152, United States Patent Application Publication No. US 2005/0209558 ("the '558 Publication"), a copy of which has been produced at CIPLA-BDI_0184988-5008.

y. DX-168, United Kingdom Patent No. GB 994,755 ("the '755 Patent"), a copy of which has been produced at CIPLA-BDI_0184742-746.

z. DX-169, European Patent Publication No. EP 1,321,159 ("the '159 Publication"), a copy of which has been produced at CIPLA-BDI_0184759-779.

aa. DX-170, International Patent Publication No. WO 2006/126965 ("the '965 Publication"), a copy of which has been produced at CIPLA-BDI_0184554-593.

bb. DX-154, United States Patent Application Publication No. US 2007/0277817 ("the '817 Publication"), a copy of which has been produced at CIPLA-BDI_0184329-337.

cc. DX-171, International Patent Application No. WO 2005/113044 ("the '044 Publication"), a copy of which has been produced at CIPLA-BDI_0184507-553.

dd. DX-083, *Metered Dose Inhalers: Actuators Old and New*, Expert Opin. Drug Deliv., 4(3):235-245 (2007) ("Lewis 2007").

ee. DX-156, United States Patent Application Publication No. US 2006/0107949 ("the '949 Publication"), a copy of which has been produced at CIPLA-BDI_0184291-314.

ff. DX-157, United States Patent Application Publication No. US 2007/0062518 ("the '518 Publication"), a copy of which has been produced at CIPLA-BDI_0185009-061.

gg. DX-158, United States Patent Application Publication No. US 2007/0210102 ("the '102 Publication"), a copy of which has been produced at 0185277-291.

5. CONTESTED FACTS

- **Teva:** See attached Exhibit A.
- **Defendants:** See attached Exhibit B.

6. WITNESSES

- **Teva:**
  - Witnesses to be called in person:
    - Declan Walsh
    - Jeffrey Karg
    - Dr. David Lewis (expert witness, see below)
    - Dr. Reynold Panettieri (expert witness, see below)
  - Witnesses to be called by deposition:
    - Priyanka Bajpayee
    - Deborah Carr
    - Jay Holt
    - [redacted]
    - Kiran Rote
  - Evidence by Written Answer:
    - [redacted]
      - [redacted]
      - [redacted]
      - [redacted]

- **Defendants:**
  - Witnesses who may be called in person:
    - Kiran Rote
    - Jay Holt
    - Deborah Carr
    - Gregor Anderson (expert witness, see below)
  - Witnesses to be called by deposition:
    - Declan Walsh
    - Jeffrey Karg
    - [redacted]

7. EXPERT WITNESSES

If any hypothetical questions are to be put to an expert witness on direct examination, they shall be written in advance and submitted to the court and counsel prior to commencement of trial except that to the extent an expert witness intends to provide opinions from the perspective of a hypothetical person of ordinary skill in the art, the parties are not required to provide questions meant to elicit those opinions so long as the opinions are clearly disclosed in the expert's reports in this matter.

The parties stipulate to the qualifications of the below-listed experts.

- **Teva:**
  - Dr. David Lewis
    - Dr. Lewis's qualifications are summarized in the attached report section and curriculum vitae.
  - Dr. Reynold Panettieri
    - Dr. Panettieri's qualifications are summarized in the attached report section and curriculum vitae.
- **Defendants:**
  - Gregor Anderson

- Mr. Anderson's qualifications are summarized in the attached report section and curriculum vitae.

8. DEPOSITIONS

- **Teva:** See attached Exhibit C.
  - **i.** Priyanka Bajpayee (Cipla)
  - **ii.** Deborah Carr (Aurobindo)
  - **iii.** Jay Holt (Aurobindo)
  - **iv.** [redacted]
  - **v.** Kiran Rote (Cipla)
- **Defendants:** See Attached Exhibit D.
  - **i.** Declan Walsh (Teva)
  - **ii.** Jeffrey Karg (Radius)
  - **iii.** [redacted]

9. EXHIBITS

Any party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to all evidentiary objections.

- **Teva:** See Attached Exhibit E.
- **Defendants:** See Attached Exhibit F.

10. SINGLE LIST OF LEGAL ISSUES

All issues shall be set forth below. The parties need not agree on any issue, and the inclusion of an issue shall not be construed as an admission that it is properly presented.

1. Whether Cipla's submission of Cipla's ANDA infringes the Asserted Claims under 35 U.S.C. § 271(e)(2)(A).

2. Whether Aurobindo's submission of Aurobindo's ANDA infringes the Asserted Claims under 35 U.S.C. § 271(e)(2)(A).

3. Whether the commercial use, manufacture, sale, offer for sale, or importation into the United States of Cipla's ANDA Products would infringe the Asserted Claims under 35 U.S.C.

§ 271(a).

4. Whether the commercial use, manufacture, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products would infringe the Asserted Claims under 35 U.S.C. § 271(a).

5. Whether Teva's allegations of infringement of the Asserted Claims of the '156 Patent under the doctrine of equivalents are barred by prosecution history estoppel with respect to the term "wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister."

6. Whether Teva's allegations of infringement of claims 3 of the '289 Patent and claims 3 and 13 of the '587 patent under the doctrine of equivalents improperly vitiate the "inner wall" limitation.

7. Whether Teva's allegations of infringement of claim 12 of the '156 patent under the doctrine of equivalents improperly vitiate the "wall surfaces" limitation.

8. Whether Teva's allegations of infringement under the doctrine of equivalents improperly ensnare the '406 Publication.

9. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims are anticipated under 35 U.S.C. § 102 based on the following grounds:

a. Whether Defendants have proven by clear and convincing evidence that claims 1-3 of the '289 Patent are anticipated by International Patent Publication No. WO 2007/124406 (the "'406 Publication").

b. Whether Defendants have proven by clear and convincing evidence that claims 1-3 and 12 of the '587 Patent are anticipated by the '406 Publication.

c. Whether Defendants have proven by clear and convincing evidence that claims 1 and 4-8 of the '289 Patent are anticipated by International Patent Publication No. WO 2003/101514 (the "'514 Publication").

d. Whether Defendants have proven by clear and convincing evidence that claims 1, 4-8, and 11-12 of the '587 Patent are anticipated by the '514 Publication.

e. Whether Defendants have proven by clear and convincing evidence that claims 1, 9 and 11-13 of the '156 Patent are anticipated by U.S. Patent Application Publication No. 2002/0047021 (the "'021 Publication").

f. Whether Defendants have proven by clear and convincing evidence that claims 1, 9, and 11-12 of the '156 Patent are anticipated by International Patent Publication No. WO 2008/119552 (the "'552 Publication").

g. Whether Defendants have proven by clear and convincing evidence that

claim 1 of the '808 Patent is anticipated by the '552 Publication.

h. Whether Defendants have proven by clear and convincing evidence that claim 1 of the '808 Patent is anticipated by U.S. Patent Application Publication No. 2002/0078950 (the "'950 Publication").

10. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims would have been obvious under 35 U.S.C. § 103(a) based on the following grounds:

a. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '289 and '587 Patents would have been obvious over the '406 Publication in combination with the knowledge of the POSA.

b. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '289 and '587 Patents would have been obvious over the '514 Publication in combination with the '406 Publication.

c. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '289 and '587 Patents would have been obvious over the '021 Publication in combination with the knowledge of the POSA.

d. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '289 and '587 Patents would have been obvious over the '514 Publication in combination with the '021 Publication.

e. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '156 Patent would have been obvious over the '552 Publication in combination with the knowledge of the POSA.

f. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '156 Patent would have been obvious over the '406 Publication in combination with the knowledge of the POSA.

g. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '808 Patent would have been obvious over the '552 Publication in combination with the knowledge of the POSA.

h. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '808 Patent would have been obvious over the '950 Publication in combination with the knowledge of the POSA.

i. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '808 Patent would have been obvious over the '406 Publication in combination with the knowledge of the POSA.

11. Whether Defendants have proven by clear and convincing evidence that asserted claim 12 of the '156 Patent is invalid because the term "the body" is indefinite under 35 U.S.C.

§ 112 ¶ 2.

12. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '808 Patent are invalid under 35 U.S.C. § 112 ¶ 1 under Teva's proposed construction of the term "counter display arranged to indicate dosage information" because the term lacks adequate written description support under that construction.

13. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims of the '808 Patent are invalid under 35 U.S.C. § 112 ¶ 1 under Teva's proposed construction of the term "counter display arranged to indicate dosage information" because the term lacks adequate enablement support under that construction.

14. Whether Teva is entitled to a declaration and judgment that Aurobindo and Cipla infringe the Asserted Claims.

15. Whether Cipla is entitled to a declaration and judgment that Cipla does not infringe the Asserted Claims.

16. Whether Aurobindo is entitled to a declaration and judgment that Aurobindo does not infringe the Asserted Claims.

17. Whether Teva is entitled to a declaration and judgment that the Asserted Claims of are not invalid.

18. Whether Defendants are entitled to a declaration and judgment that the Asserted Claims are invalid.

19. Whether Teva is entitled to an order, under 35 U.S.C. § 271(e)(4)(A), that the effective date(s) of FDA's approval of Aurobindo's and Cipla's ANDAs shall be a date not earlier than the latest expiration date of the '289, '587, '156, and '808 Patents, including any adjustments, extensions, or exclusivities.

20. Whether Cipla is entitled to a declaration and judgment that Cipla has the lawful right to manufacture, import, use, sell, and/or offer to sell Cipla's ANDA Product in the United States following approval from FDA.

21. Whether Aurobindo is entitled to a declaration and judgment that Aurobindo has the lawful right to manufacture, import, use, sell, and/or offer to sell Aurobindo's ANDA Product in the United States following approval from FDA.

22. Whether Teva is entitled to an injunction, under 35 U.S.C. §§ 271(e)(4)(B) and 283, prohibiting Aurobindo and Cipla and their officers, agents, servants, and employees from manufacturing, using, offering for sale, selling, or importing into the United States Aurobindo's and Cipla's ANDA Products prior to the latest expiration date of the '289, '587, '156, and '808 Patents, including any adjustments, extensions, or exclusivities.

23. Whether Cipla is entitled to an injunction that Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them be

preliminarily and permanently enjoined from threatening or initiating litigation alleging infringement of the '289, '587, '156, and '808 Patents against Cipla or any of its customers, dealers, or supplies, or any prospective or present sellers, dealers, distributors, or customers, or charging them, orally or in writing, with infringement of the '289, '587, '156, and '808 Patents.

24. Whether Aurobindo is entitled to an injunction that Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them be preliminarily and permanently enjoined from threatening or initiating litigation alleging infringement of the '289, '587, '156, and '808 Patents against Aurobindo or any of its customers, dealers, or supplies, or any prospective or present sellers, dealers, distributors, or customers, or charging them, orally or in writing, with infringement of the '289, '587, '156, and '808 Patents.

25. Whether Teva is entitled to an award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

26. Whether Teva is entitled to an award of costs under Federal Rule of Civil Procedure 54(d)(1).

27. Whether Cipla is entitled to an award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

28. Whether Cipla is entitled to an award of costs under Federal Rule of Civil Procedure 54(d)(1).

29. Whether Aurobindo is entitled to an award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

30. Whether Aurobindo is entitled to an award of costs under Federal Rule of Civil Procedure 54(d)(1).

11. PROPOSED FACTS FOR JUDICIAL NOTICE

- See attached Exhibit G.

12. MISCELLANEOUS

Presentation of Evidence.

The parties have agreed that the order of the presentation of evidence will follow the burden of proof as follows:

Phase	Description
Phase I	Teva's presentation of Asserted Patents and case-in-chief on infringement.
Phase II	Defendants' response on infringement and case-in-chief on invalidity.

Phase III	Teva's response on invalidity and case-in-chief on objective indicia of non-obviousness.
Phase IV	Defendants' response on any objective indicia of non-obviousness asserted by Teva.

Deadlines for Exchanging Witnesses and Objections.

The parties have agreed to the following procedures and deadlines for exchanging witnesses and objections to witnesses.

Exhibit/Demonstrative	Exchange Deadline	Objection Deadline
Live witness testimony	8:00 PM ET, two days before the intended testimony	
Affirmatively designated deposition testimony/testimony by written response	8:00 PM ET, three days before the intended testimony	7:00 PM ET, two days before the intended use
Counter-designated deposition testimony	7:00 PM ET, two days before the intended testimony	7:00 PM ET, one day before the intended testimony
Counter-counter designated deposition testimony	7:00 PM ET, one day before the intended testimony	9:00 PM ET, one day before the intended testimony

Deadlines for Exchanging Exhibits and Demonstratives and Objections.

The parties have agreed to the following additional procedures and deadlines for exchanging exhibits and demonstratives and objections to exhibits and demonstratives:

Exhibit/Demonstrative	Exchange Deadline	Objection Deadline
Exhibits to be used in connection with opening argument.	8:00 PM ET, two days before the intended use	N/A
Exhibits to be used in connection with direct examination	8:00 PM ET, two days before the intended use	7:00 PM ET, one day before the intended use
Demonstratives* to be used in connection with direct examination	8:00 PM ET, two days before the intended use	7:00 PM ET, one day before the intended use
Demonstratives* to be used in	8:00 PM ET, one day before	9:00 PM ET, one day

connection with cross-examination	the intended use	before the intended use

* This provision does not apply to demonstratives created during testimony, which need not be disclosed. This provision also does not apply to highlighting, ballooning, arrowing, call-outs, etc., of exhibits or testimony, which are not required to be provided to the other side in advance of their use.

Meeting and Conferring.

The parties will meet and confer to resolve any objections to witnesses, exhibits, and demonstrative at 9:30 PM ET the evening before the intended testimony or use of the exhibits and demonstratives. If good-faith efforts to resolve the objections fail, the objecting party shall bring its objections to the Court's attention prior to the witness being called to the witness stand.

Exhibits and Demonstratives.

Any joint trial exhibits are identified using "JTX" numbers. Teva's trial exhibits are identified using "PTX" numbers, and Teva's trial demonstratives shall be identified using "PDX" numbers. Defendants' trial exhibits shall be identified using "DTX" numbers, and Defendants' trial demonstratives shall be identified using "DDX" numbers. The parties' exhibits are listed in the attachments to Section 9. The parties' demonstratives need not be listed on their exhibit lists.

Legible copies of documents may be offered and received into evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or in the circumstances it would be unfair to admit the copy in lieu of the original. Legible copies of U.S. and foreign patents, and the contents of associated file histories, may be offered and received into evidence in lieu of certified copies thereof, subject to all other objections which might be made to admissibility of certified copies. The parties agree that either side may offer into evidence the opposing sides' pleadings (including discovery responses, contentions, and filings) and do not need to list such pleadings on the exhibit list. The parties agree that a copy of each of the Asserted Patents their file histories, and assignment records (JTX-001-018) shall be admitted.

13. TRIAL COUNSEL

- **Plaintiff Teva:**
    - Walsh Pizzi O'Reilly Falanga LLP
        - Liza M. Walsh
        - Katelyn O'Reilly
        - William T. Walsh
    - Williams & Connolly LLP
        - David I. Berl

        - Benjamin M. Greenblum
        - Elise M. Baumgarten
        - Kathryn S. Kayali
        - Ben Picozzi
        - Ricardo Leyva

- **Defendant Cipla:**
    - Rivkin Radler, LLP
        - Gregory D. Miller
        - Gene Y. Kang
    - Knobbe, Martens, Olson & Bear, LLP
        - William R. Zimmerman
        - Joseph M. Reisman
        - William O. Adams
        - Jonathan Bachand
        - Karen M. Cassidy Selvaggio
        - Brandon G. Smith
        - Nick Belair
        - Ashley C. Morales

- **Defendant Aurobindo:**
    - McNeely Hare & War, LLP
        - William D. Hare
        - Christopher Casieri

14. <u>BIFURCATION</u>

The parties agree that there is no need for bifurcation.

15. ESTIMATED LENGTH OF TRIAL

Plaintiffs propose that the parties complete their opening statements and presentation of evidence in three days of 6.5 hours each. Because Plaintiffs are still asserting thirty-six claims across four patents, Defendants propose that the parties complete their trial presentations, including opening statements, presentation of evidence, and closing arguments in five trial days of 6.5 hours each.

Plaintiffs propose that the parties present a short closing upon conclusion of the evidence followed by a lengthier closing argument at the conclusion of post-trial briefing. Defendants propose that closing arguments be heard upon conclusion of the evidence during the trial.

16. TRIAL DATE

The parties propose the week of November 7, 2022, subject to the Court's availability.

EXCEPT AS SET FORTH SPECIFICALLY HEREIN, NO AMENDMENT TO THIS PRETRIAL ORDER SHALL BE PERMITTED UNLESS THE COURT DETERMINES THAT MANIFEST INJUSTICE WOULD RESULT IF THE AMENDMENT WERE DISALLOWED. THE COURT MAY FROM TIME TO TIME SCHEDULE CONFERENCES AS MAY BE REQUIRED EITHER ON ITS OWN MOTION OR AT THE REQUEST OF COUNSEL.

Dated: September 1, 2022

Respectfully submitted,

s/ Liza M. Walsh

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Attorneys for Defendant Cipla Ltd.

SO ORDERED:

_____

HON. MICHAEL A. HAMMER, U.S.M.J.